



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

M.D.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/367,712 08/18/99 SEFTON

J 17224 (AP)

HM22/0721

ROBERT J BARAN
ALLERGAN SALES INC
2525 DUPONT DRIVE T2 7H
IRVINE CA 92612

EXAMINER

RADIO, B

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

5
07/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/367,712

Applicant(s)
Sefton

Examiner
Barbara Badio

Group Art Unit
1616



☐ Responsive to communication(s) filed on _____

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3, 5-8, and 10-13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 5-8, and 10-13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1616

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

2. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 5 which is dependent on claim 2 recites "fluocinolone acetonide".

Fluocinolone acetonide was deleted from claim 2 by applicant's amendment.

Claim Rejections - 35 USC § 103

3. The rejection of claims 4 and 9 under 35 USC 103(a) over Yamamoto ('906) and Nagpal et al. ('279) in combination is made moot by the cancellation of the instant claims.

4. The rejection of claims 1-3, 5-8 and 10-11 under 35 USC 103(a) over Yamamoto ('906) and Nagpal et al. ('279) in combination is maintained and claims

Art Unit: 1616

12-13 are rejected under 35 USC 103(a) over Yamamoto ('906) and Nagpal et al. ('279) in combination.

Applicant argues that he has demonstrated that mid- or high-potency corticosteroids in combination with tazarotene provide more effective treatment of psoriasis than tazarotene, alone or with a low-potency corticosteroid or in combination with a placebo. Applicant argues that there are fewer adverse events such as burning, pruritus and erythema. The argument was considered but not persuasive for the following reasons.

Applicant's argument is based on the degree of effectiveness of the combination of two compositions known in the art to be useful in the treatment of psoriasis. The issue is not whether the prior art teaches one compound is more potent or more effective than the other. The issue is whether the prior art teaching makes it obvious to one having ordinary skill in the art at the time of the invention that the combination of a corticosteroid and tazarotene would be useful in the treatment of proliferative skin diseases such as psoriasis. The examiner's position is that (1) Yamamoto teaches the use of any adrenocortical hormone in the treatment of psoriasis and exemplifies a number of preferred compounds such as betamethasone valerate and fluocinolone, both recited by the instant invention (see col. 2, lines 14-19) and (2) Nagpal teaches the use of tazarotene in the treatment of psoriasis. Thus, the combined use of

Art Unit: 1616

tazarotene and an adrenocortical hormone in the treatment of psoriasis would have been obvious to one having ordinary skill in the art at the time of the invention.

It would have been obvious to the skilled artisan that Yamamoto recognizes the use of both mid and high potency corticosteroids in the treatment of psoriasis based on the exemplified compounds (see col. 2, lines 1-19). The determination of the degree of efficacy of each of these compounds in treating psoriasis involves only routine analysis and is within the level of skill of the ordinary artisan. The determination of which combination of corticosteroid and tazarotene is most effective and/or which results in the lowest adverse effect is also within the level of skill of the ordinary artisan. Therefore, the fact that applicant has shown that mid- or high-potency corticosteroid in combination with tazarotene gives the best results while achieving the lowest adverse effects is not considered a patentable invention.

For these reasons and those given in Paper No. 3, the rejection of claims 1-3, 5-8 and 10-11 under 35 USC 103(a) over Yamamoto ('906) and Nagpal et al. ('279) in combination is maintained and claims 12-13 are rejected under 35 USC 103(a) over Yamamoto ('906) and Nagpal et al. ('279) in combination.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith ('074) or Sequeira et al. ('529) in combination with Nagpal et al. ('279).

Art Unit: 1616

Both Smith and Sequeira et al. teach the use of corticosteroids, such as alclometasone dipropionate and betamethasone dipropionate in the treatment of psoriasis (see '074, col. 4, lines 47-67; '529, col. 1, lines 36-63).

Nagpal et al. teach it is known in the art to use tazarotene in the treatment of psoriasis (col. 1, lines 42-47).

The instant claims differ from the cited references by reciting the combined use of a corticosteroid and tazarotene in the treatment of skin diseases such as psoriasis. However, it is known in the art as indicated above to use each of the recited compound in the treatment of psoriasis. The combination of two compounds/compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose would have been obvious to one having ordinary skill in the art. In re Kerkhoven, 205 USPQ 1069 (CCPA 1980). Thus, the claimed composition is prima facie obvious based on the combined teachings of the above references. The ordinary artisan would be motivated to use combination treatment for a number of reasons including the reduction of the adverse effect of each of the compound utilized.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1616

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

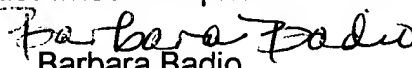
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry Contacts

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Barbara Badio
Primary Examiner
Art Unit 1616

July 20, 2000